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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/031,801 03/15/93 KUCHERLAPATI

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EXAMINER

HM12/0620

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ART UNIT

PAPER NUMBER

1632

DATE MAILED:

06/20/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/031,801

Applicant(s)

KUCHERLAPATI ET AL.

Examiner

Anne M Beckerleg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 68,83-88,95-97 and 104-109 is/are pending in the application.
- 4a) Of the above claim(s) 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 83-88, 95-97 and 104-109 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

Applicant's amendment and response of 4/9/01 has been entered. Claims 83-88, 95-97, and 104-109 are pending and active in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in a previous office action.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 83 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 -5 of U.S. Patent No. 6,114,598, 9/5/00. Although the conflicting claims are not identical, they are not patentably distinct from each other for the

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following reasons. The patented claims are broader than the instant claims in that they read on a transgenic mouse which have at least one inactivated endogenous heavy chain locus. The instant claims recite that both copies are inactivated. However, the specification of the 6,114,598 patent clearly teaches that both copies of the endogenous heavy chain can be inactivated. Thus, the patented claims encompasses the instant claim and renders it obvious.

***Claim Rejections - 35 USC § 112***

The rejection of claims 86-88, 95-97, and 104-109 under 35 U.S.C. 112, first paragraph, for scope of enablement is maintained. Applicant's arguments and claim amendments have been fully considered but have not been found persuasive in overcoming the instant rejection for the reasons of record as discussed in detail below.

The applicant argues that the specification provides sufficient guidance for YACs which include at least 5 VH genes and that applicant's amendment to the claims now limits the VH genes to those found on human chromosome 14. The claims as amended continue to read broadly on germline segments of the Ig heavy or light chain locus including the D segment and J segment genes and the C $\mu$  constant region operably linked to one or more human V segment genes which can include the entire Ig locus minus the switch regions and constant regions 3' of the C $\mu$  gene. The specification, including the working examples and Figure 16, discloses a single YAC vector which comprises a Spe restriction fragment of the germline human heavy chain Ig locus which

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includes V6, the D segment genes, the J segment genes, C $\mu$  and C $\delta$ . The specification does not provide sufficient guidance concerning the construction of YAC vectors including additional V segments up to and including the entire V region. At the time of filing, physical mapping, cloning, and sequencing of the entire human heavy chain variable locus had not been accomplished. In addition, as late as 1993, the actual number of functional V segment genes was unknown and complicated by the presence of large numbers of non-functional pseudogenes (Matsuda et al. (1993) Nature Genetics, Vol. 3, 88-94). The specification provides no guidance as to the sequence of variable regions distal to the D heavy chain region on chromosome 14. The specification does not provide guidance for obtaining YACs which include the germline sequence of chromosome 14 that comprises variable regions genes other than the YAC disclosed in Figure 16, or provide guidance for functional heavy chain variable gene sequences which could be linked to the germline sequence shown in Figure 16. Thus, the specification only teaches a single YAC vector useful for the instant invention and fails to teach how to make a YAC or any other vector which comprises the germline sequence of chromosome 14 including the entire D region and J region genes, the C $\mu$  region, and any or all variable region genes. In regards to the additional YACs referred to by the applicant on page 56-59 of the specification, the 205 kb YAC contains a deletion that removes some of the D gene cluster, while the 215 kb YAC has a deletion that removes the mu gene. Thus, neither of these YACs meets the limitations of the applicant's claims which recite a DNA sequence identical to or which contains a germline DNA sequence of human

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chromosome 14 from the D segment genes through the J segment genes and the constant region genes through C $\mu$ .

Therefore, in view of the lack of teachings in both the art and the specification for the complete sequence of the functional V segment genes on chromosome 14, the lack of guidance for operably linking nucleotide sequences encoding V genes distal to the D heavy region, the lack of guidance for any YAC vector other than that disclosed in Figure 16, and the breadth of the claims, the skilled artisan would not have predicted success in obtaining a YAC or any other DNA sequence encoding the germline D region, J region, and C $\mu$  gene operably linked to any or all V segment genes and as such it would have required undue experimentation to practice the invention as claimed.

Claims 86-88, 95-97 and 104-109 stand rejected under 35 U.S.C. 112, first paragraph, for lack of written description. The applicant has not presented any arguments in response to this rejection, therefore, the rejection is maintained for reasons of record as found in paper no. 50. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision.

***Claim Rejections - 35 USC § 102***

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The rejection of claims 83 and 85 under 35 USC 102(e) over U.S. Patent No. 5,591,669, hereafter referred to as Krimpenfort et al. is withdrawn in view of applicant's arguments.

***Claim Rejections - 35 USC § 103***

The rejection of claim 84 under 35 U.S.C. 103 over U.S. Patent No. 5,591,669 as applied to claims 83 and 85 above and further in view of U.S. Patent No. 5,591,669 is withdrawn in view of applicant's arguments.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Beckerleg, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Karen Hauda, can be reached at (703) 305-6608. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The official fax number is (703) 308-4242.

Dr. A.M.S. Beckerleg

A handwritten signature in black ink, appearing to read "AMSBeeleg", with a long horizontal flourish extending to the right.